K041392

NOV - 8 2004

510(k) Summary of Safety and Effectiveness

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Robert K. Larsen, Regulatory Affairs Manager
Preparation Date: May 21, 2004

Device Name:

Trade Name:	SonX 35 Ultrasonic Bleaching System
Common Name:	Ultrasonic Energy Source for Bleaching Teeth
Product Classification:	Toothbrush, Powered

Legally Marketed Predicate Devices for Substantial Equivalence:

- Sonex Ultrasonic Toothbrush, Manufactured by Sonex Intl., Corp.
510(k) Number: K913724

Rationale for Substantial Equivalence:

The aforementioned devices share similarities for use in the oral cavity for the purpose of improving the appearance of teeth. These devices feature similar modes of: energy delivery in the oral cavity, delivered energy output, and frequency of delivered energy.

Description of Submitted Device:

The SonX 35 Ultrasonic Bleaching System is a device used in the application of dentifrice compositions for the purpose of whitening teeth. This device aids in the performance of these compositions by providing energy in the form of ultrasonic wave energy. Transducers that are fully encased in the portion of the tray external to the patient generate the ultrasonic energy at a frequency that is sinusoidally cycled between 25,000 and 30,000 hertz. Electrical pulses of a voltage not exceeding 7VDC and 300mA current are supplied to the transducers by means of a separate power source unit, which delivers the energy by means of insulated conductors attached to an appendage of the tray device. All electrical connections are external of the patient, and the transducer electrical supply is electrically isolated from the main power supply.

For the purpose of tooth whitening, the ultrasonic energy is provided for the purpose of accelerating the formation and physical movement of oxygen free-radicals from the peroxide active ingredient throughout the whitening composition towards and within the tooth structure. The oxygen free-radicals then work to improve the appearance

and health of teeth by reacting with stain molecules and bacteria in and on the teeth, altering chemical bonds within these materials, destroying the bacteria and changing the optical properties of the stains such that they become transparent and appear to loose their color.

This device differs from the predicate devices in that the ultrasonic energy is not transmitted directly to the tooth structure through solid appendages of the device, but delivers the energy primarily to a dentifrice medium that is in contact with, and acts on, the tooth structure.

Intended Uses of the SonX 35 Ultrasonic Bleaching System:

The SonX 35 Ultrasonic Bleaching System is used to accelerate the action of a tooth whitening medium by introducing energy into said medium in the form of ultrasonic vibrational impulses at a frequency between 25000 and 30000 hertz, improving the appearance of teeth. This intended use is similar to those of the predicate devices to which substantial equivalence is claimed.

Technological Characteristics of Substantial Equivalence:

The Sonex Ultrasonic Toothbrush uses two forms of vibrational energy to clean tooth structure. One form of energy is ultrasonic at a frequency of 1.6MHz, which is transmitted from the unit into the tooth structure and surrounding gum tissue for the purpose of displacing plaque bacteria. The second form is sonic vibration of the cleaning bristles at 18 kHz for the purpose of dislodging physical particles. This device is a rechargeable battery operated hand-held unit.

Performance Standards:

The SonX 35 Ultrasonic Bleaching System complies with the performance requirements of 21 CFR 1050, and the electrical safety requirements of IEC 60601-1 and IEC 60601-2-5.

Clinical Performance Data

See Part 7: Performance Data

Conclusion

The SonX 35 Ultrasonic Bleaching System is substantially equivalent to the aforementioned devices with regards to purpose of the device and means by which that purpose is accomplished without raising any new issues regarding safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Mr. Robert K. Larsen
Regulatory Affairs Manger
CAO Group, Incorporated
8683 South 700 West
Sandy, Utah 84070

Re: K041392
Trade/Device Names: SonX 35 Ultrasonic Bleaching System
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: November 03, 2004
Received: November 03, 2004

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your device contains the following component whose regulatory status has not yet been determined: hydrogen peroxide. In late 1991, the Food and Drug Administration sent letters to manufacturers and/or distributors of tooth whitening preparations (such as the bleaching gel contained in your device) advising them that the agency considered the product drugs and "new drugs" as defined in the Federal Food, Drug, and Cosmetic Act (the act). Under the provisions of the act, a "new drug" may not be legally marketed in this country unless it is the subject of an approved New Drug Application (NDA). The NDA must contain adequate scientific data, including clinical trials, which establish that a product is safe and effective for its intended use.

As a result of a court case brought by one of the manufacturers, the agency agreed to further evaluate the status of tooth whitener preparations to determine whether they should be regulated as

"new drugs" or cosmetics. The agency has not yet completed that further evaluation. The status of hydrogen peroxide, the whitening component of your device, is unresolved at this time.

Our substantially equivalent determination does not apply to the whitening component(s) of your device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other

general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041392

Device Name: *SonX 35 Ultrasonic Bleaching System*

Indications For Use:

The SonX 35 Ultrasonic Bleaching System is used to accelerate the action of a tooth bleaching medium by introducing energy into said medium in the form of ultrasonic vibrational impulses at a frequency cycled between 25000 and 30000 hertz, improving the appearance of teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041392

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)